PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
01005-0121WP		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US00/35560	29/12/2000	30/12/1999
International Patent Classification (IPC) or national classification and IPC A61K9/00		
Applicant ACRYMED et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

I	☒	Basis of the report
II	☐	Priority
III	☒	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	☐	Lack of unity of invention
V	☒	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
VI	☐	Certain documents cited
VII	☐	Certain defects in the international application
VIII	☐	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
19/06/2001	02.04.2002
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Pregetter, M Telephone No. +49 89 2399 8719

Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/US00/35560

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:
Description, pages:

1-42 as originally filed

Claims, No.:

1-20 as originally filed

Drawings, sheets:

1/4-4/4 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 13-20, concerning industrial applicability.

because:

☒ the said international application, or the said claims Nos. 13-20 relate to the following subject matter which does not require an international preliminary examination (*specify*):
see separate sheet

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos. .

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N) Yes: Claims

	No:	Claims	1-20
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-20
Industrial applicability (IA)	Yes:	Claims	1-12
	No:	Claims	

2. Citations and explanations
see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. Claims 13-20 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(i) PCT).

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:

   D1: GB-A-2 024 012 (JOHNSON & JOHNSON) 9 January 1980 (1980-01-09)
   D2: EP-A-0 500 387 (EXOXEMIS INC) 26 August 1992 (1992-08-26)
   D3: US-A-5 407 685 (KRALOVIC RAYMOND C ET AL) 18 April 1995 (1995-04-18) cited in the application
   D4: US-A-5 928 174 (GIBBINS BRUCE L) 27 July 1999 (1999-07-27) cited in the application
   D5: US-A-5 076 265 (WOKALEK HEINRICH) 31 December 1991 (1991-12-31)
   D6: US-A-4 306 551 (HYMES ALAN C ET AL) 22 December 1981 (1981-12-22)

2. The subject-matter of present claim 1 is not new according to Article 33(2) PCT. Present claim 1 defines a matrix comprising a polymer network, a non-gellable polysaccharide and oxygen. This matrix must be suitable for the delivery of oxygen.
   A gas will necessarily be delivered as soon as a concentration ingredient is provided. Consequently, if the matrix is placed in a vacuum, it will be able to delivery oxygen even if said matrix comprises only minor amounts of oxygen.
   Two of the documents cited in the search report already disclose wound dressings comprising a polymeric network and a non-gellable polysaccharide. D4 defines such a wound dressing in claim 6. D6 prefers karaya gum as the non-gellable polysaccharide (claims 1, 4 and 6). Since the matrices of D4 and D6 are not

prepared under a protected atmosphere (e.g. nitrogen or argon), they will comprise oxygen, since oxygen is present in the normal air. Consequently the documents D4 and D6 are considered to be novelty destroying for present claim 1.

3. The subject-matter of present claim 13 is not new according to Article 33(2) PCT. Present claim 13 only defines a method using a biocompatible matrix. The term "matrix" is very broad. It is considered that the documents D1-D6 are novelty destroying for present claim 13. Cf. e.g. D1, p.1, l.5-7 and example; D2 claim 34; D3, claims 1 and 29; D4, col.1, l.4-10 and claim 6; D5, claims 1, 6 and 8; D6, examples and col.2, l.14-20.

4. With regard to dependent claims 2-12 and 14-20 it is noted that a positive opinion can only be given, if dependent claims refer to independent claims that meet the requirements of the PCT. However, at least some of these dependent claims do not contain any features which, in combination with the features of any claim to which they refer, might establish novelty and an inventive step over D1-D4 (Articles 33(2) and 33(3) PCT).

5. For the assessment of the present claims 13-20 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

6. Claims 14-20 refer to claim 13. Claim 13 defines a method of treating compromised tissue (i.e. a process). Claims 14-20 define a matrix (i.e. a product). Claims can refer only to claims of the same category. This change of category renders the subject-matter of claims 14-20 unclear (Article 6 PCT). For the purpose of examination it has been assumed that claims 14-20 define a "method according to claim 13 (or 17) wherein ....".